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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,065

04/08/2005

Takaaki Terahara

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20529 7590 03/11/2009

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EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

03/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,065	Applicant(s) TERAHARA ET AL.	
	Examiner TRISTAN J. MAHYERA	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/1/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/01/2008 has been entered.

It should be noted that the Examiner has changed.

Status of Claims

Claims 1 and 3-11 are pending and examined on the merits. Claims 1 and 3 have been amended.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d) is acknowledged.

Response to Arguments and Amendments

Applicants respectfully make the following arguments:

(A) Applicants state that no *prima facie* case of obviousness has been shown by the examiner regarding the amended limitation to claim 1, specifically, "...a basic nitrogen-including polymer that includes a basic nitrogen and having no self-adhesion property" and existing limitation including "...no substantial carboxyl group and hydroxyl group in the molecule". Applicants further argue that Terahara et al. disclose in Example 5 and 6 the use of an acrylate polymer, "Duro-Tak 387-2287", which has carboxyl groups and therefore differs from the "acrylic polymer including no substantial carboxyl group and hydroxyl group in the molecule and having self-adhesion properties" as required in the present claims.

(B) Applicants state no reasonable expectation of success to arrive at the present claims exists. Applicants point to Examples 5 and 6 in Terahara et al. that allegedly teach away from the instant invention by showing the use of a rubber polymer in combination with Duro-Tak 387-2287 an acrylic polymer that is "...clearly excluded from the scope of the present claims".

(C) Applicants argue unexpected results, specifically that the instant invention clearly shows superior skin permeation rates when compared to the drug permeation rates for compositions lacking at least one of the components.

With regard to (A), Applicants correctly state that "[n]either Chono et al., nor Hirano et al. disclose the component of "a basic nitrogen-including polymer including a basic nitrogen and having no self- adhesion property", however, as this was a limitation previously found in claim 2 and incorporated into claim 1, the new rejection of Claim 1,

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i.e. Chono in view of Hirano and in view of Terahara et al., teaches a basic nitrogen-including polymer that includes a basic nitrogen and having no self-adhesion property.

With respect to the Terahara et al. argument, the Examiner would like to clarify that Terahara et al. is used as a teaching for the inclusion of the basic nitrogen-including polymer (methyl methacrylate - butyl methacrylate - dimethylaminoethyl methacrylate terpolymer (pg. 6, lines 22-25), not for the Duro-Tak 387-2287. The acrylic polymer including no substantial carboxyl group and hydroxyl group in the molecule and having self-adhesion properties is taught by Chono et al. in p[0030], which suggests the use of a copolymer of 2-ethylhexyl acrylate and vinyl acetate as the acrylic polymer, both of which are considered to have the same properties as that of the instant application (i.e. being substantially free of carboxyl and hydroxyl groups).

The use of the term “substantial” in claim 1, while not indefinite, is extremely broad. The term “substantially” is often used in conjunction with another term to describe a particular characteristic of the claimed invention. It is a broad term. In re Nehrenberg, 280 F.2d 161, 126 USPQ 383 (CCPA 1960). The court held that the limitation “to substantially increase the efficiency of the compound as a copper extractant” was definite in view of the general guidelines contained in the specification. In re Mattison, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). See e.g. MPEP 2173.05(b). In this case, no limits have been placed on the term “substantial”, nor does the specification clarify in any manner what is included or excluded from the broad meaning. The Duro-Tak 387-2287 acrylic polymer, while it may have some carboxyl

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groups, is interpreted in light of the term “substantial” as not falling outside of the claimed limitation (i.e. no substantial carboxyl groups).

With regard to (B), the Examiner has demonstrated that the Duro-Tak 387-2287 polymer is not excluded from the scope of the claims, as discussed in (A) above. In addition or in the alternative, the Examples in Terahara et al. and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments as patents are relevant for all they contain (see e.g. MPEP 2123). Terahara et al. specifically teaches the rubber in combination with methacrylate polymers, such as 2-methylhexyl acrylate, methyl methacrylate and butyl methacrylate. See e.g. page 14 lines 6-12. This is further explicitly shown in Example 2 with SIS and Duro-Tak 87-2097, which has no carboxyl groups. As these are fully encompassed by the broad interpretation of the claims it is reasonable that a person skilled in the art would use an acrylic polymer having no substantial carboxyl groups and would use the polymers of Chono et al. as a starting point or the above disclosed polymers in Terahara et al.

With regard to (C), the Data in Table 1 (Ex. 1-6) has a skin permeation rate range from 6.0 to 19.6, while Tables 2 and 3, which are directed to compositions lacking at least one component have a skin permeation range from 3.0 to 14.0. This data only shows an increase in skin permeation for those examples above 14, namely Examples 1-3, as the remaining Examples are equal to or less than the skin permeation rates of Examples 4-6. The difference between the combinations in the prior art and the instant is not sufficient to show unexpected results because using the instant invention in

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examples 4-6 has an equal to or less than skin permeation rate when compared to Comparative example 1, which has a rate of 14. To show unexpected results of a skin permeation rate, the instant invention would need to demonstrate a rate that is not known in the art or sufficiently different, i.e. higher in this case, from rates known in the art, regardless of components, which is not done by the cited examples.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 3-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (EP 1 201 232) in view of Hirano et al. (US 2002/0102290) and in view of Terahara et al. (CA 2428181).

With respect to claims 1 and 5-9, Chono et al. discloses a patch comprising a backing layer and an adhesive layer disposed on the backing layer and compounded with an adhesive agent and pergolide and/or a pharmaceutically acceptable salt thereof [0014], [0015], wherein the adhesive layer comprises an acrylic polymer being a copolymer that includes 2-ethylhexyl acrylate and vinyl acetate [0030], therefore is considered to be having self-adhesion properties as well as being substantially free of carboxyl and hydroxyl groups, and a rubber polymer (SIS) [0030], [0031]. Chono et al. also discloses the acrylic polymer being 10-98% by weight and the rubber polymer being 10-60% by weight [0031].

Chono et al. fails to expressly disclose the inclusion of a basic nitrogen-including polymer that includes a basic nitrogen and having no self-adhesion property, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1.

Terahara et al. discloses a patch having a basic nitrogen-including polymer being a methyl methacrylate- butyl methacrylate- dimethylaminoethyl methacrylate

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terpolymer, or polyvinyl acetal diethylamino acetate. (pg. 6, lines 24-25). Terahara et al. further illustrates in Example 5, a formulation having pergolide mesilate that includes an acrylate polymer, a rubber (SIS) and a basic nitrogen-including polymer, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1.

It would have been obvious to one of ordinary skill in the art to include a basic nitrogen-including polymer and modify the amount thereof, in order to enhance the skin permeability of the drug, as taught by Terahara et al. (pg. 4, line 21 - pg. 5, line 9). Absent any evidence to the contrary, and based upon the teachings of the prior art, specifically the inclusion of a basic nitrogen-including polymer which is known for use in the patch arts, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Chono et al. fails to expressly disclose the weight content ratio of the acrylic polymer to the rubber polymer being only from 1:1 to 1:9. However, with the ranges described above, the weight ratio content of the acrylic polymer to the rubber polymer can be fall between 1:1 and 1:9. Further, Hirano et al. demonstrates in Example 1, a pressure-sensitive adhesive comprising an acrylate polymer (2-ethylhexyl acrylate-vinyl acetate copolymer) and a rubber polymer (polyisobutylene and styrene/isoprene/styrene block copolymer), wherein the weight ratio of acrylic polymer to rubber polymer is 1:2.

It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug [0031]. Further, since it has been held that where

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the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

With respect to claim 4, the modified Chono et al. discloses the adhesive layer comprising an alicyclic saturated hydrocarbon resin-based tackifier [0032]. The modified Chono et al. discloses the tackifier being from 10-70% by weight of the total composition of the adhesive layer, therefore demonstrating the ability to attain a weight ratio of the total content of acrylic polymer and rubber polymer to the content of the tackifier being from 1:1 to 1:9.

With respect to claims 10 and 11, the modified Chono et al. discloses the adhesive agent comprises an organic acid (acetic acid) [0017].

It would have been obvious to one of ordinary skill in the art to modify the amount of tackifier in order to provide the desired amount of adhesion with the consideration of irritation to the skin at a peeling time [0032]. Further, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Absent any evidence to the contrary, and based upon the teachings of the prior art, specifically the use of a tackifier in the patch arts, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The Examiner will not hold any double patenting rejections in abeyance.

Claims 1 and 5-8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 8 and 12 of copending Application No. 10/469,612 (amendment filed on 10/4/07) in view of Hirano et al. and in view of Terahara et al. (CA 2428181).

This is a provisional obviousness-type double patenting rejection.

With respect to claim 1 of the current application, claims 1, 8 and 12 of Application No. 10/469,612 (amended claims filed 2/13/2009) discloses:

(claim 1) **A patch comprising a support (functionally equivalent to a backing layer), and an adhesive layer** laid on the support the adhesive layer **(adhesive agent)** consisting of at least one drug, optionally one or more pharmaceutically acceptable excipient, and an adhesive base consisting of at least one acrylic polymer selected from the group consisting of a **2-ethylhexyl acrylate-N-vinyl-2-pyrrolidone-1,6-hexane glycol dimethacrylate copolymer**, an aminoalkylmethacrylate copolymer E and a **2-ethylhexyl acrylate-vinyl acetate copolymer**, the acrylic polymer substantially having no carboxyl group and no hydroxyl group in molecules thereof, **and a rubber-based polymer** selected from the group consisting of a **styrene-isoprene-styrene block copolymer**, a **polyisobutylene**, an **isoprene rubber**, a **styrene-butadiene-styrene block copolymer** and a **styrene-butadiene rubber**.

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(claim 8) wherein **said drug is at least one selected from** the group consisting of **pergolide, pharmacologically acceptable salts of pergolide**, oxybutynin, and pharmacologically acceptable salts of oxybutynin.

(claim 12) wherein said drug is selected from the group consisting of pergolide and pharmaceutically acceptable salts of pergolide.

Claims 1, 8 and 12 of Application No. 10/469,612 fail to expressly disclose the weight ratio of content of the acrylic polymer to content of the rubber polymer being from 1:1 to 1:9. Hirano et al. demonstrates in Example 1, a pressure-sensitive adhesive comprising an acrylate polymer (2-ethylhexyl acrylate-vinyl acetate copolymer) and a rubber polymer (polyisobutylene and styrene/isoprene/styrene block copolymer), wherein the weight ratio of acrylic polymer to rubber polymer is 1:2. It would have been obvious to one of ordinary skill in the art to modify the weight ratio of content of the acrylic polymer to the rubber polymer to create an adhesive layer having good permeability of the drug. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claims 1, 8 and 12 of Application No. 10/469,612 fail to expressly disclose the inclusion of a basic nitrogen-including polymer that includes a basic nitrogen and having no self-adhesion property, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1.

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Terahara et al. discloses a patch having a basic nitrogen-including polymer being a methyl methacrylate- butyl methacrylate- dimethylaminoethyl methacrylate terpolymer, or polyvinyl acetal diethylamino acetate. (pg. 6, lines 24-25). Terahara et al. further illustrates in Example 5, a formulation having pergolide mesilate that includes a an acrylate polymer, a rubber (SIS) and a basic nitrogen-including polymer, wherein the weight ratio of the total content of the acrylic polymer and the rubber polymer to the content of the basic nitrogen-including polymer is from 9:1 to 1:1.

It would have been obvious to one of ordinary skill in the art to include a basic nitrogen-including polymer and modify the amount thereof, in order to enhance the skin permeability of the drug, as taught by Terahara et al. (pg. 4, line 21 - pg. 5, line 9). Absent any evidence to the contrary, and based upon the teachings of the prior art, specifically the inclusion of a basic nitrogen-including polymer which is known for use in the patch arts, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax

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phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615